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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,876	04/10/2001	Steven L. Stice	P 0280088	1054

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EXAMINER

CROUCH, DEBORAH

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 11/19/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/828,876

Applicant(s)

STICE ET AL.

Examiner

Deborah Crouch, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 and 35-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Applicant's election without traverse of Group II, claims 28-34 in Paper No. 3, filed October 30, 2002 is acknowledged. Claims 1-27 and 35-77 are withdrawn from consideration.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,235,970 B1. . An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims encompass the subject matter of claims 1-18 of '970.

The present claims are drawn to methods of producing a CICM cell line comprising inserting a desired differentiated mammalian cell or cell nucleus into an enucleated oocyte

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of the same species as the mammalian cells or cell nucleus to form an NT unit, activating the NT unit, culturing the NT unit until greater than the 2-cell stage; and culturing cells obtained from the cultured NT unit to obtain a CICM cell line. The proliferating differentiated somatic donor cell or donor cell nucleus of claims 1-18 in '970 are within the scope of differentiated mammalian cell or cell nucleus of the present claims. The greater than 2-cell stage, as in the present claims, is encompassed by the limitation in '970 of culturing until at least a size suitable for obtaining ICM cells, or culturing to form a blastocyst. The culturing step of the present claims is defined by the present specification to take place on a feeder layer with growth to at least 50 cells as claimed in claims 2, 16, and 17 of '970. The present claim to "differentiated cell" is defined by the present specification to be any one of the cells specifically claimed in claim 3 of '970. The present specification defines transgenic as being any modification as claimed in claims 5-9 and 11 of '970. The term mammal in the present claims is defined by the present specification to be any one of the mammals of claims 10 and 12-14 in '970. The present specification also defines the mammalian CICM cell line as being bovine or porcine as in claim 18 of '970.

Therefore at the time of the instant invention, it would have been obvious to the ordinary artisan to make the present methods and products given claims 1-18 of '970.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28, 30 and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of , does not reasonably provide enablement for methods of producing a CICM cell line comprising introducing a proliferating differentiated somatic mammalian donor cell or donor cell nucleus into an enucleated

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mammalian oocyte of the same species to produce an NT unit, activating the NT unit, culturing said activated NT unit until at least a size suitable for obtaining ICM cells, and isolating and culturing ICM cells to obtain a cultured C1CM cell line. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Germ cells, encompassed by the present claims, being the donor cell or the donor nucleus are not enabled. Germ cells are haploid, and it is unpredictable that the insertion into of a haploid nucleus into an enucleated oocyte would result in embryonic growth, as required for the formation of inner cell mass cells. Further, it is unpredictable that any cellular growth of a haploid cell would result in the development of inner cell mass cells, which compose an embryonic structure. There is no evidence of record or in the art that a haploid nucleus can support embryonic development to the point where inner cell mass cells form in the embryo. ICM cells, required for the present invention, are only found in later embryos, usually at the blastocyst stage. ICM cells do not exist at the early embryo stage.

Thus at the time of the instant invention, the skilled artisan would need to engage in an undue amount of experimentation without a predictable degree of success to implement the present claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 29 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sims et al (1993) Proceed. Natl. Acad. Sci. 90, 6143-6147.

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Claim 29 is drawn to a CICM cell line. However, as claim 29 is a product by process claim, a teaching of the same product obtained by a different method serves as anticipatory art against the claim.

Sims et al teach the culture of ICM cells as cell lines 6-10 (page 6146, col. 1, parag. 2 and table 4). Claims 29 does not distinguish from the ICM cell line taught by Sims et al. Without a distinction which indicates a structural or functional difference between the claimed cell line and that disclosed in Sims et al, Sims et al clearly anticipates the claimed invention.

Claims 33 and 34 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kono et al (1995) Experimental Cell Res. 221, 478-485.

Claims 33 and 34 are drawn to differentiated cells and human cells made by a claimed process. However, as a product by process claim, a teaching of the same product by a different method serves as anticipatory art.

Kono teaches differentiated hepatocytes from normal human tissue (page 479, col. 1, parag. 2, lines 1-4). Claims 33 and 34 do not distinguish from the hepatocytes taught by Kono. Without a distinction, which indicates a structural or functional difference between the claimed differentiated cells and those taught by Kono, Kono clearly anticipates the claimed invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sims et al (1993) Proceed. Natl. Acad. Sci. 90, 6143-6147 in view of Lovell-Badge et al, Cold Spring

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Harbor Symp. Quant. Biol., Vol. 50, pages 707-711, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York, 1985.

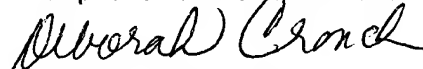
Claim 31 is drawn to a transgenic C1CM cell line.

Sims et al teach the culture of ICM cells as cell lines 6-10 (page 6146, col. 1, parag. 2 and table 4). However, Sims does not teach a transgenic C1CM cell line. Lovell-Badge teaches mouse embryonic stem cells, which have been, transformed with a DNA sequence encoding human type II collagen gene (page 708, col. 2, parag. 3, lines 1-4). Motivation is provided by Sims et al stating that embryonic stem cells are derived from ICM cells, and that transgenic embryonic stem cells would be advantageous for the production of cattle (page 6146, col. 2, parag. 6, line 4 to page 6147, line 2). Thus, it would have been obvious to the ordinary artisan at the time of the instant invention to produce a transgenic C1CM cell line for use in the production of transgenic non-human mammals.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 703-308-1126. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

dc
November 15, 2002